

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

BIOFER S.P.A.,

Plaintiff,

v.

VIFOR (INTERNATIONAL) AG,

Defendant.

Civil Action No. 1:22-CV-02180-AMD-SJB

STIPULATION AND ORDER OF NON-INFRINGEMENT OF THE '320 PATENT

Plaintiff Biofer S.p.A. (“Plaintiff” or “Biofer”) and Defendant Vifor (International) AG, (“Defendant” or “Vifor”), by and through their counsel, hereby stipulate and move for entry of final judgment of non-infringement of all asserted claims of U.S. Patent No. 8,759,320 (the “Asserted Patent”) based on the Court’s *Markman* Order (Dkt. 139) with respect to the term “pH between 7.0 and 9.0”. In support of this stipulation, the Parties state as follows:

WHEREAS, in this Action, Plaintiff has asserted infringement by Defendant of process claims 1-16, 19-21, and 23-25 of the Asserted Patent (“the Asserted Claims”) by making, using, offering to sell, selling, and/or importing the Injectafer® product and/or the Injectafer® active pharmaceutical ingredient (“API”) and/or by inducing infringement of American Regent, Inc.;

WHEREAS, Defendant has asserted it does not infringe any of the Asserted Claims either directly, indirectly, literally or under the doctrine of equivalents and does not induce American Regent, Inc., or any other third party, to infringe the Asserted Claims, that the Asserted Claims are invalid, and the Asserted Patent is unenforceable;

WHEREAS, the term “pH between 7.0 and 9.0” appears in independent claim 1 of the Asserted Patent. All other Asserted Claims depend, either directly or indirectly, from claim 1, and,

therefore, also include the term “pH between 7.0 and 9.0”;

WHEREAS, the Parties’ disputed claim construction issues were briefed and a *Markman* hearing was held on August 3, 2023;

WHEREAS, on March 29, 2024, the Court issued its *Markman* Order (Dkt. 139) in which it stated that (a) the term “pH between 7.0 and 9.0” means “a pH maintained in the interval separating 7.0 and 9.0” (*id.* at 10), (b) it “adopts Vifor’s proposed construction” (*id.* at 16), and (c) “the Court finds that the intrinsic evidence supports that the pH range must be maintained throughout the process” (*id.* at 12);

WHEREAS, Plaintiff acknowledges that under the aforesaid *Markman* Order with respect to the term “pH between 7.0 and 9.0”, Plaintiff cannot establish infringement of any of the Asserted Claims of the Asserted Patent, specifically and solely because Plaintiff cannot establish that the pH is maintained throughout the process in the interval separating 7.0 and 9.0;

WHEREAS, Plaintiff intends to appeal the Court’s *Markman* Order with respect to the term “pH between 7.0 and 9.0”;

NOW THEREFORE, the Parties hereby stipulate and agree, subject to the approval of the Court, as follows:

1. The Parties stipulate and agree that under the *Markman* Order with respect to the term “pH between 7.0 and 9.0”, Plaintiff cannot prove that Defendant infringes the Asserted Claims, either directly, indirectly, literally or under the doctrine of equivalents.

2. The Parties therefore request that the Court enter final judgment for Defendant and against Plaintiff on Plaintiff’s claims for infringement of the Asserted Patent, and declare that Defendant does not infringe any of the Asserted Claims of the Asserted Patent based on the *Markman* Order with respect to the term “pH between 7.0 and 9.0”.

3. The Court has not made any findings on invalidity or unenforceability and there are no invalidity or unenforceability issues to appeal at this time.

4. The Parties stipulate that all other contentions regarding claim construction, infringement and non-infringement, invalidity and validity, as well as unenforceability and enforceability of the Asserted Patent are expressly reserved. Specifically, the Parties recognize that Defendant contends that the Asserted Claims of the Asserted Patent are not infringed under any claim construction by the Court or proposed by the Parties, that the Asserted Claims are invalid and unenforceable, and that other defenses bar Plaintiff's claims. The Parties recognize that Plaintiff disputes each of these contentions. The Parties agree that if the case is remanded, Defendant's affirmative defenses and counterclaims will be reinstated, Defendant has the right to re-assert any and all of its contentions and grounds for non-infringement, invalidity and unenforceability, and Plaintiff has the right to challenge these contentions and grounds. The Parties further stipulate that if the case is remanded, the Court's May 30, 2024 oral Orders on the parties' respective motions to compel (as articulated in the May 30, 2024 status conference transcript), remain in effect.

5 Notwithstanding the foregoing, and for the avoidance of doubt, Plaintiff states specifically that it disagrees with the *Markman* Order including, *inter alia*, with respect to the Court's construction of the term "pH between 7.0 and 9.0", including with respect to any requirement that "the pH range must be maintained throughout the process", (*see* D.I. 139 at 12), and that it intends to challenge the *Markman* Order on the Court's construction of the term "pH between 7.0 and 9.0" on appeal. Nothing herein shall be deemed to be an admission, acceptance, or adoption by Plaintiff that Defendant does not infringe the Asserted Patent, other than as stipulated herein based on the *Markman* Order with respect to the term "pH between 7.0 and 9.0".

Plaintiff expressly reserves its right to challenge all other claim constructions issued by the Court in its *Markman* Order on an appeal, except for the term “instant-by-instant”, which the Court construed in accordance with the Parties’ agreed upon construction.

6. The Parties expressly reserve all appellate rights including, but not limited to, the right to appeal the Court’s claim constructions in the Court’s *Markman* Order to the United States Court of Appeals for the Federal Circuit upon entry of final judgment.

7. In the event the U.S. Court of Appeals for the Federal Circuit reverses, vacates, modifies, or remands the Court’s *Markman* Order with respect to the term “pH between 7.0 and 9.0”, the Parties agree that (a) the final judgment of noninfringement set forth herein should not be affirmed, and (b) this Stipulation terminates, except for Paragraphs 4 and 5 of this Stipulation, which remain in effect.

8. The Parties agree that entry of judgment of non-infringement would be a final judgment that adjudicates all the claims for all the parties to this Action. Defendant agrees that its counterclaims shall be dismissed without prejudice. The Parties agree that the Court should enter final judgment of non-infringement in favor of Defendant consistent with this Stipulation with respect to all Asserted Claims in the First Amended Complaint (Dkt. 90).

Dated: July 11, 2024

By: /s/ Jonathan D. Ball

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DONE AND ORDERED on this ____ day of August, 2024

Honorable Ann M. Donnelly
UNITED STATES DISTRICT JUDGE